# A Database of Exposures in the Rubber Manufacturing Industry: Design and Quality Control

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The concerted action EXASRUB was initiated to create a database management system for information on occupational hygiene measurements that could be used to develop exposure models in the European rubber manufacturing industry. Quality of coding was assessed by calculating percentages of agreement and Cohen's kappa statistics (K) for an intra- and intercentre recoding of randomly selected subsets of the measurements. In a 6-month period, 59 609 measurements from 523 surveys in 333 factories from as early as 1956 to 2003 were coded. The database consists primarily of measurements of N-nitrosamines (36%), rubber dust (23%), solvents (14%) and rubber fumes (10%). Coding of epidemiologically relevant information was done consistently with inter-centre  $\kappa$  between 0.86 and 1.00. For occupational hygiene information, values of  $\kappa$  were estimated to be between 0.67 and 1.00. The proposed method resulted in a large quantity of exposure measurements with auxiliary information of varying completeness and quality. Analyses showed that coding of epidemiologically relevant information in such a multi-centre, multi-country study was coded consistently. Larger errors however, occurred in coding of occupational hygiene information. This was primarily caused by lack of information in the primary records of measurements, emphasizing the importance of having a universal system in place to collect and store measurement information by occupational hygienists for future use.

Keywords: database; data quality; exposure assessment; multi-centre study; rubber manufacturing industry

# INTRODUCTION

In 1982, a working group convened by the International Agency for Research on Cancer (IARC)

reviewed the evidence for carcinogenic risks to workers in the rubber manufacturing industry. There was sufficient evidence for increased occurrence of urinary bladder cancer and leukaemia. In addition, there was limited evidence of a higher prevalence of cancer of the lung and the stomach (IARC, 1982). Overall, the rubber manufacturing industry was classified as 'entailing exposures that are carcinogenic to humans (Group 1)' (IARC, 1987). In 1998, Kogevinas and co-workers reviewed all studies published after the IARC review of 1982. They confirmed the findings of the IARC monograph, although they noted that the magnitude of the risks varied considerably between

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studies. They also observed an increased risk for laryngeal cancer, which IARC did not identify in the 1982 evaluation. Due to the long latency time between exposure and the manifestation of solid tumours, it remained unclear whether the observed cancer risks in recent epidemiological studies were related to exposures from the remote past, as discussed by Straughan (1998) and Carlo et al. (1993), or from exposures that are still present today. This question is particularly relevant since the rubber industry has made a considerable effort to reduce exposures through implementation of engineering control measures and to remove known carcinogens (naphtalamine, benzene, asbestos) from the production process (Wacker et al., 1987; Dost et al., 2000; Vermeulen et al., 2000a; Veys, 2004). Furthermore, Kogevinas et al. (1998) noted the absence of accurate and detailed information on exposures, which precluded the linkage of specific exposures to the increased risk of cancers, thereby precluding targeted preventative measures.

Recently, several European countries (Sweden, UK, Poland and Germany) initiated prospective cohort studies to address the risk in the contemporary rubber industry. Due to expected lower risks for the development of malignancies, it is anticipated that larger numbers of subjects than those available in each cohort separately will be needed to accurately evaluate risk, especially for less common cancers. Combining the above-mentioned cohorts for pooled or meta-analyses can potentially overcome this lack of power. In order to perform such combined analyses, exposure information must be comparable across different studies. To facilitate such a combined analyses, the concerted action 'Improved Exposure Assessment for Prospective Cohort Studies and Exposure Control in the Rubber Manufacturing Industry' (EXASRUB) was initiated within the European Union 5th framework, in the Quality of Life and Management of Living Resources Programme. The goal of this project was to combine exposure data (with auxiliary information on methods, control measures and process information) from Germany, UK, the Netherlands, Sweden and Poland into a single occupational hygiene database that could be used to develop a common method of exposure assessment for epidemiological studies, to provide information on trends in occupational exposures to a number of chemical agents, and to disseminate information on occupational control hygiene measures that were recently implemented in the European rubber industry.

This paper addresses the method for data collection and coding of exposure determinants and describes the structure of the EXASRUB database. Furthermore, the quality of the coding in several centres is assessed, and problems in coding of determinants of exposure in such a multi-centre, multi-country study are described.

### **METHODS**

Structure of the database

The EXASRUB database management system (DBMS) is a Microsoft Access'97 application, which facilitated the entry of measurement information and auxiliary occupational hygiene information into a database using a common method of data-entry in all participating countries. The flow chart of the whole EXASRUB project is presented in Fig. 1, showing the steps involved in assembling the database.

Because of the large number of measurements that we expected to enter into the database, a hierarchical data model was developed (Fig. 2). This structure of the DBMS (i) minimized repetitive data-entry (thereby reducing the amount of errors) and (ii) enabled a combination of manual and automated coding of information. Furthermore, part of the information that was requested in the DBMS was pre-programmed in the so-called 'drop-down menus' to reduce the amount of typing, as well as to minimize the number of errors which could potentially occur while manually entering or copying large volumes of information.

As proposed in a study of the asphalt industry (Burstyn *et al.*, 2000), several country-specific versions, or satellite-versions, of the EXASRUB database were developed to (i) further minimize the amount of repetitive data-entry by adding country-specific information to the satellite-versions, (ii) make country-specific adaptations to the DBMS for coding of specific industrial hygiene information, (iii) allow for simultaneous entry of data in all participating institutes and (iv) simultaneously update, or make additions to, parts of the database without making it temporarily unavailable to other participating centres.

We tried to anticipate an optimal data model by examining easily accessible data before the basic structures of the DBMS were designed. Nevertheless, the structure of the database was designed to be somewhat flexible, because assumptions had to be made about the data that were to be entered into the database; naturally, not all possibilities could be anticipated (Burstyn *et al.*, 2000).

A list of variables coded in the EXASRUB database is shown in the Appendix. A selection of these variables [marked with an asterisk (\*)] is defined as the core information, which was part of the 'the minimum set of data elements which should form the basis of workplace exposure databases on chemical agents, so as to help towards validation, harmonization and exchange of information on workplace exposure data' (Rajan *et al.*, 1997). These core-variables represented the minimum amount of information that a measurement was required to have, before it was accepted into the EXASRUB database. In addition to these core-data elements, a worker identification

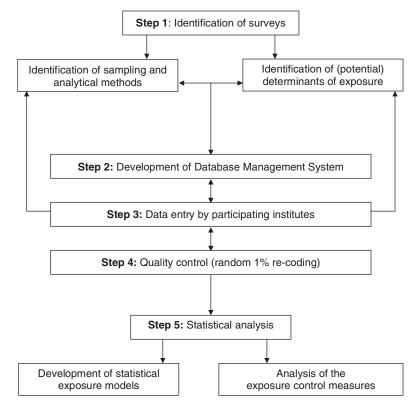
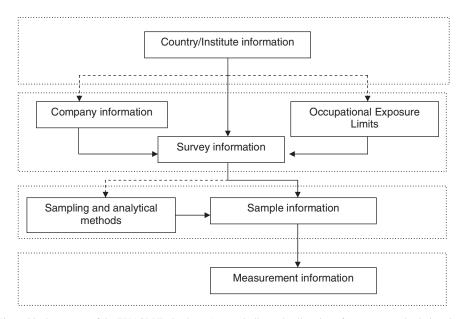


Fig. 1. Stepwise procedure of the EXASRUB project.



**Fig. 2.** Hierarchical structure of the EXASRUB database (arrows indicate the direction of 'one-to-many' relations between data elements, and dashed arrows indicate data elements that are not part of the hierarchical structure).

number and a location identification number were also coded in the EXASRUB database to identify the number of measured workers and locations in each survey, as well as to identify repeated measurements that were done on the same worker or location, and thus enable analyses that allow for such dependencies in the data. Thus, for personal measurements, we aimed to be able to quantify the within- and between-worker variance components (Kromhout *et al.*, 1993) and for stationary measurements the within- and between-location variance components. This was done by assigning successive numbers to

new workers and locations, while assigning the same number when more measurements were reported on the same worker or location. This enabled us to collect information on the number of measured workers and on repeated measurement designs applied in the surveys, without collecting personal information (i.e. worker name, date of birth, etc.). An analogous procedure was applied to factory information, where a specific factory identification number was assigned, together with determinants on factory-level, to all measurements done in the same factory to be able to analyse within- and between-factory variance components without retaining names and locations of the companies.

# Data-entry procedures

A country-specific satellite version of the DBMS was sent to all participating institutes, where local experts entered the measurement information and auxiliary information of the available surveys in the rubber manufacturing industry. Data were either added to the database manually, by coding the information directly from the original datasheets; automated, by developing an algorithm which coded the available data from the original digital format into the format designed for the EXASRUB project; or a combination of both, where part of the information was added from a data file to the database using an algorithm, while other information was coded manually to complete the information in the EXASRUB database.

Before the actual data-entry period started, a training session with all members of the EXASRUB consortium was organized to familiarize all coders with the EXASRUB-DBMS, optimize the structure of the DBMS, to eliminate errors that still existed in the application, and to include additional parameters to the drop-down menus.

After this initial meeting, a new update of the satellite versions was distributed to all participating centres and data-entry commenced. When problems, such as a missing option in the drop-down menus occurred (e.g. missing chemical agent, missing sampling device), the centre sent their version of the DBMS to the coordinating centre by e-mail. There, the appropriate changes were made to the DBMS and it was returned to the original centre. In addition, all other centres were contacted about this addition to one of the satellite versions to enable other centres to update their satellite version accordingly, if needed.

When the participating centres entered all data, the satellite versions of the DBMS were combined into the final EXASRUB database at the coordinating centre.

Quality control of the coding of measurement data

Three approaches were pursued to analyse the quality of the data-entry process. First, 46 samples were

randomly selected from each country by the coordinating centre, this was weighted by the size of each survey (N = 230;  $\sim 1\%$  of the total number of individual samples in the EXASRUB database). The identifying numbers of these samples were sent to each centre, where the original coder, using the same procedure that was used in the initial coding of the data, coded them again. Re-coding was done manually in Sweden, UK and the Netherlands, while in Germany the same algorithm was applied to the dataset as was done in the initial coding. In Poland, an algorithm was used to code part of the data while some determinants of exposure were added manually, as was also done in the initial coding. Second, another 46 samples were randomly selected by the coordinating centre (weighted by survey size) from the measurements in UK. The UK-centre then sent copies of the original datasheets for these 46 samples to the coordinating centre, where the person who originally coded the Dutch data re-coded this sample of data from UK. The coding was done by the same coder using the same procedure, but was blinded to the original coding. Third, one survey was executed by a Dutch researcher in a Swedish rubber factory. This survey was inadvertently coded by both the Dutch and the Swedish centres, and independently added to the EXASRUB database. This survey was retrieved from the EXASRUB database and differences between the two coding results were analysed. Only information on aggregated level and no individual measurement data was available to the Swedish centre at time of data-entry, so differences in coding could not be analysed for specific occupational hygiene information.

Percentage of agreement and Cohen's (weighted) kappa ( $\kappa$ ) (Fleiss, 1981) were calculated to analyse the quality of coding available in the EXASRUB database.

### RESULTS

Description of the EXASRUB database

The measurements in the EXASRUB database have been collected from very different sources in the participating countries. The majority (83.3%) of all Dutch measurements came from two large research surveys (Kromhout et al., 1994; Vermeulen et al., 2000a, b), and the rest from unpublished research reports {internal report (7%), MSc theses [including an EXASRUB survey (F. de Vocht, D. Huizer, M. Prause, K. Jackobsson, B. Peplonska, K. Straif and H. Kromhout, submitted for publication)] (4%) and an internship report (1%)}, from two reports from an Occupational Health service (3%), and from the Dutch labour inspectorate (2%). Almost all of the German data came from the MEGA database (99.6%) (Stamm, 2000), but a few extra measurements were also obtained from an EXASRUB survey (F. de Vocht, D. Huizer, M. Prause,

K. Jakobsson, B. Peplonska, K. Straif and H. Kromhout, submitted for publication) in Germany (0.4%). The 67% of the measurements from UK were from those collected by the British Rubber Manufacturer's Association (BRMA) (Dost et al., 2000). In addition, one series of small surveys (33%) was from the National Exposure Database (Burns et al., 1989). The Polish measurements were primarily from a study published by Szadkowska-Stanczyk et al. (2001) (86%). Another 9% has also been published previously (Rogaczewska and Ligocka, 1994), and the remaining 5% of the measurements from Poland were recorded in an unpublished Nofer Institute of Occupational Medicine report (4%), a sanitary hygienic stationary report (0.4%) and an EXASRUB survey (F. de Vocht, D. Huizer, M. Prause, K. Jakobsson, B. Peplonska, K. Straif and H. Kromhout, submitted for publication) (0.6%). The 2% of the Swedish data comes from the same EXASRUB survey, with all other Swedish measurements recovered from internal factory reports (98%).

The characteristics of the EXASRUB database are presented in Table 1. A total of 59 609 measurements were collected and coded. The database contains measurements from 523 surveys in 333 factories and covers in particular the period from 1965 to 2003; in addition it contains 10 Swedish measurements from 1956: 40% of the measurements were taken in factories where general rubber goods were produced and 59% in tyre-production factories. For only one survey (0.3% of measurements), the industrial sector could not be determined. Ninety-nine percent of the measurements were coded as representative sampling, with only 0.7% reported as originating from worstcase sampling. In 0.3% of measurements, it could not be determined whether the measurements were representative or worst-case. The number of personal and stationary samples were equally distributed: 49 and 51%, respectively. Most of the measurements originated from sampling strategies that involved some randomization (i.e. randomly selected workers, sites or both). However, it has to be noted that the sampling strategy was undetermined for a large part of the measurements (38%).

Specific *N*-nitrosamine measurements constituted ~36% of the EXASRUB database (21 202 measurements), followed by 13 655 inhalable aerosol measurements, 8615 specific solvents measurements and 5932 cyclohexane-soluble matter measurements. Not all 59 609 measurements are obtained from independent samples, since many samples have been analysed for several chemical agents (e.g. multiple *N*-nitrosamines, solvents and specific components of dust). More specifically, 10 849 Dutch measurements are from 2795 independent samples, 19 480 German measurements are from 3697 samples and 10 701 UK measurements are from 6161 samples. Measurements were done on 6520 different workers and 4971

different sites. In Poland, the majority of samples are analysed for one chemical agent, with 13 807 measurement results on 12 182 independent samples, while in Sweden 4772 measurement results are from 2260 samples. The frequencies of independent samples for the four most commonly monitored agents in the EXASRUB database are shown in Figs 3a–d.

Inhalable aerosol measurements were done using a PAS-6 sampling device for 91% of the Dutch measurements, while 75 and 97% of these measurements in Germany and UK, respectively, have been collected using a seven-hole sampler, 80% of the Swedish measurements were collected using a Millipore openface sampler, and 99% of Polish measurements were obtained using yet another sampling head that was common in Eastern Europe.

Quality control of the coding of measurement data

For seven (15%) of the randomly selected measurements from UK, the original datasheets could not be retrieved, and consequently results presented are for 39 measurements. Intra-centre recoding, which was done blind for the original coding, showed that coding of the determinants of exposure was done consistently, with percentages of agreement and Cohen's weighted  $\kappa$  between 85 and 100% and 0.67 and 1.00, respectively (Table 2).

Inter-centre coding showed that coding of 'higher level' determinants (such as industrial sector, factory and department), that are useful for epidemiological studies, was done similarly, with percentage of agreement between 87 and 100%. If more detailed information for occupational hygienic studies such as factory- and department-specific determinants were coded [such as process during measurements and presence (and type) of local exhaust ventilation], agreement decreased to 67% in UK and 48% in Sweden.

### Online access

A complete project overview and the Technical Annex of the EXASRUB project are available on the internet: http://exasrub.iras.uu.nl. In addition, graphs with individual measured concentrations of the most prominent chemical agents [rubber process dust, rubber fumes, specific solvents (heptane and toluene) and specific *N*-nitrosamines (NMor and NDMA)] can be selected per country, industrial sector, department and time period using an interactive tool at the same webpage.

### DISCUSSION

### EXASRUB database

This study aimed at creating a method of collecting exposure measurements and auxiliary information

Table 1. Characteristics of the EXASRUB database by countries

	Netherlands	Germany	UK	Poland	Sweden
N (measurements)	10 849	19 480	10 701	13 807	4772
N (samples)	2795	3697	6161	12 182	2260
Surveys	18	55	42	7	401
Factories	33	13	257	3	27
Workers	754	1439	3986	104	237
Sites (stationary samples)	245	2263	2175	139	149
Time period	1984–2003	1974–2003	1977–2002	1970–2003	(1956) 1965–2003
Industrial sector (%)					
General rubber goods	48.9	39.5	54.4	7.1	89.7
Tyres	49.3	60.5	45.6	92.9	10.4
Unknown	1.8	_	_	_	_
Purpose of survey (%)					
Research	70.5	0.4	_	13.9	23.5
Evaluation of controls	23.8	_	3.9	_	_
Compliance testing (regulator)	4.1	89.2	9.8	86.1	12.3
Compliance testing (companies)	0.2	10.4	61.6	_	51.2
Concern	0.9	_	20.7	_	0.5
Follow-up of complaints	_	_	_	_	7.6
Unknown	0.5	_	4.1	_	4.9
Sampling strategies (%)					
Representative	97.5	99.7	99.9	100.0	98.1
Worst-case	2.5	0.3	0.1	_	1.9
Personal	72.1	50.4	67.7	6.9	68.6
Stationary	14.7	49.3	32.3	92.6	15.1
Source-oriented	13.2	0.4	_	0.5	16.3
Random days	50.1	_	_	11.0	_
Random workers	43.1	0.4	_	3.0	2.7
Random days and workers	1.8	99.6	_	_	95.8
Everybody	3.7	_	_	_	1.1
Undefined	1.2	_	100.0	86.1	0.5
Chemical substances					
Inhalable aerosol fraction	2307	188	4310	6407	443
<i>N</i> -nitrosamines <sup>a</sup>	395	18 619	595	413	1180
Rubber fumes/CSF <sup>b</sup>	1628	_	3965	225	114
Specific solvents <sup>c</sup>	4149	_	1533	1060	1873

<sup>&</sup>lt;sup>a</sup>NDBA (11%), NDEA (11%), NDMA (11%), NDPA (10%), NEPA (9%), NMEA (1%), NMor (11%), NMPA (9%), Npip (11%), Npyr (10%).

from different sources within and outside the European rubber manufacturing industry. The approach of using satellite databases to simultaneously collect measurement data, as used before in the asphalt industry (Burstyn  $et\ al.$ , 2000), proved to be successful for collecting a large volume of measurements and auxiliary data in the European rubber manufacturing industry. In a 6-month period,  $\sim\!60\,000$  measurements from 27 095 independent samples for a

number of important chemical agents were recorded, covering almost four decades. This time period (1965–2003) covers the relevant exposure period for exposures that may be related to contemporary cancer risks in this industry. All auxiliary information was coded using a standardized format. The collected data conformed to the minimal requirement for core information proposed by Rajan *et al.* (1997). We feel that the described method embodies a good

<sup>&</sup>lt;sup>b</sup>Cyclohexane soluble fraction.

<sup>&</sup>lt;sup>c</sup>Primarily toluene (15%), heptane (10%), benzene (7%), tri-chloroethene (6%), xylene (5%) and tri-chloropentane (5%).

Table 2. Percentage of agreement and [Cohen's (weighted) kappa] between initial coding and second coding of a randomly selected 46 samples

Type of comparison (determinant)	Netherlands	Germany	UK	Poland	Sweden
Intra-centre <sup>a</sup>					
Industrial sector	93 (0.86)	100 (1.00)	100 (1.00)	100 (1.00)	100 (1.00)
Factory	100 (1.00)	100 (1.00)	99 (0.98)	100 (1.00)	100 (1.00)
Department	100 (1.00)	100 (1.00)	100 (1.00)	100 (1.00)	100 (1.00)
Process	100 (1.00)	100 (1.00)	97 (0.97)	100 (1.00)	100 (1.00)
General dilution ventilation	85 (0.67)	100 (1.00)	100 (1.00)	100 (1.00)	100 (1.00)
Open doors or windows	91 (0.91)	100 (1.00)	100 (1.00)	100 (1.00)	100 (1.00)
Lev <sup>b</sup>	93	100	100	100	93
Respirator	98 (0.96)	100 (1.00)	100 (1.00)	96	100 (1.00)
Inter-centre <sup>c</sup>					
Industrial sector		_	100	_	100
Factory		_	100	_	_
Department		_	87	_	100
Process		_	67	_	48
General dilution		_	96	_	_
Open doors or windows		_	93	_	_
Lev <sup>b</sup>		_	72 (0.45)	_	_

<sup>&</sup>lt;sup>a</sup>Based on 39 measurements.

balance between database flexibility and data security for manual entry of the data, as discussed by Burstyn et al. (2000). It should be noted that by also allowing a computer algorithm to be used to code part of the data, measurements could be added to the database with parts of the core data missing or that were spelled differently to those coded in the pre-programmed 'drop-down menus'. Checking the algorithms would have minimized data cleaning when all data was collected, but would also have been very time-consuming at the start of the project. Not allowing the use of the algorithms to add data to the database might have minimized the amount of entry errors, but would have greatly increased the time needed for manual data-entry.

Consequently, the database still contained errors at the end of the data-entry period and a period of data cleaning was required before the database could be analysed. The use of the satellite versions of the DBMS however, allowed for checking and cleaning of data during the data-entry period, without interrupting data-entry in other countries. Furthermore, since errors in coding could easily be solved, we feel that overall a lot of time was gained by allowing the use of these algorithms. Nonetheless, all these complications can be avoided if standard international procedures for storage and coding of occupational hygiene data were to be implemented (Rajan et al., 1997).

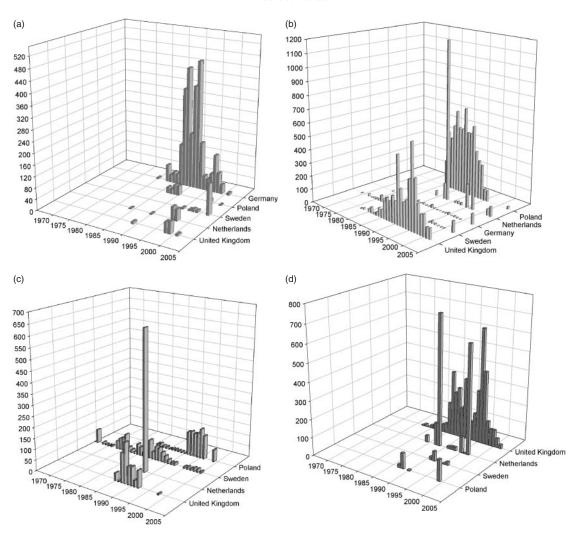
Not only the number of collected measurements and the time periods when they were collected

differed between the different countries, but large differences were also found in the type of chemical agents collected, depending on nationally set priorities and research interest of particular investigators. For example, N-nitrosamine measurements were primarily collected in Germany (Straif et al., 2000a,b), while in UK, measurements of rubber process dust and rubber fumes were made (Dost et al., 2000; Straughan and Sorahan, 2000). In the Netherlands, several industry-wide surveys were conducted, yielding measurements of a number of specific solvents (Kromhout et al., 1994), inhalable aerosol (Kromhout et al., 1994; Vermeulen et al., 2000a), rubber fumes (Kromhout et al., 1994; Vermeulen et al., 2001) and dermal exposure to cyclohexane-soluble matter (Kromhout et al., 1994; Vermeulen et al., 2000a). In Poland, most collected data were stationary dust measurements (Szadkowska-Stanczyk et al., 2001), as dictated by regulatory agencies and available technology.

Furthermore, measured concentrations cannot be compared directly between countries because of the differences in sampling devices used to measure exposures. This is most prominent for measurements of inhalable aerosol and its cyclohexane-soluble fraction where [except for two small Dutch studies (n = 49 and n = 318, respectively) aimed at simultaneously collecting inhalable aerosol measurements with different sampling devices] different devices were used in various countries. This makes it difficult to distinguish between actual differences in exposure between

<sup>&</sup>lt;sup>b</sup>Local exhaust ventilation.

<sup>&</sup>lt;sup>c</sup>Second coding done by the coordinating Dutch centre.



**Fig. 3.** (a) Distribution of individual *N*-nitrosamine samples (multiple *N*-nitrosamines can be measured per sample) in the EXASRUB database by calendar period and country. (b) Distribution of inhalable aerosol measurements in the EXASRUB database by calendar period and country. (c) Distribution of specific solvent samples (multiple specific solvents can be measured per sample) in the EXASRUB database by calendar period and country. (d) Distribution of cyclohexane soluble fraction measurements in the EXASRUB database by calendar period and country.

countries and differences in the performances of different sampling devices that are known to exist (Kenny et al., 1997). To estimate the magnitude of these differences, we conducted a small project that measured inhalable aerosol in four rubber manufacturing companies in the Netherlands, Sweden, Germany and Poland simultaneously with the PAS-6, Millipore open-face (25 and 37 mm), Seven-hole, IOM and the Polish sampling devices, and related them to a reference sampler (CALTOOL) (F. de Vocht, D. Huizer, M. Prause, K. Jakobsson, B. Peplonska, K. Straif and H. Kromhout, submitted for publication). This study showed that there are significant differences in the performance of personal inhalable aerosol samplers: consequently, studies on levels of exposure to rubber dust in different countries

cannot be compared directly. However, performance ratios were calculated for each sampler that will be used to adjust measurements in the rubber manufacturing industry to CALTOOL-concentrations that can be mutually compared.

# Quality control of the coding procedures

Overall, the agreement between the first and the second coding exercises within each research centre was good. A perfect agreement and reproducibility were observed for the coding exercises in Germany. This is not surprising because in Germany the coding was done by applying the same computer algorithm to the appropriate data from the MEGA database in both instances. Between-centre coding also showed a very good agreement for epidemiologically relevant

determinants of exposure such as industrial sector, factory and department. However, for occupational hygiene information the agreement was considerably worse, yet still satisfactory. Most of these differences arose from the lack of information on the original datasheets, or because information was very hard to identify on a datasheet. Furthermore, original coders who were familiar with the situation, i.e. the factory or the specific process, can use their expertise to supplement information not directly available on the datasheet, and thus not available to the second coder. Consequently, it is more likely that the assessment by the original coder (familiar with workplace where the data originated) can be expected to be more accurate (Stewart and Stewart, 1994). The large differences in the quality of occupational hygiene datasheets, or the way they are used, is one of the major problems of retrospective exposure assessment and was noted before for the UK data in the EXASRUB database (Dost et al., 2000), as well as in several other studies (Rajan et al., 1997; Brederode et al., 2001; Caldwell et al., 2001; Cherrie et al., 2001). Therefore, in future studies, it is recommended to systematically record whether professional judgement was used to enter supplemental information that was not directly available on the datasheet.

# CONCLUSIONS

Creating a method to collect measurement information from different sources using a common method of data-entry is an essential first step before different cohorts in the rubber manufacturing industry can be pooled and any meaningful analyses for epidemiological studies or exposure control can be performed. Using this method, we succeeded in collecting large quantities of measurement data with standard contextual data, which provides a wealth of information about occupational exposures in the European rubber manufacturing industry since the 1960s.

Furthermore, the coding/re-coding exercises suggest that the quality of the coding of the measurements in the EXASRUB database was good for epidemiologically relevant information, both within a centre as well as between centres. Differences between both coding exercises occurred more often for more detailed, process-related determinants of exposure, and were more prominent when the second coding was done at a different centre. This emphasizes the importance of having a universal system in place to collect and store measurement information by occupational hygienists and others for future use.

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### APPENDIX

List of variables coded in EXASRUB

	Core information
Country/institute information	
Country identification number	*
Country name	*
Research-centre which performs data-entry	*
Address of research-centre	
Area code of research-centre	
City where research-centre is located	
Name of contact person at research-centre	
Telephone number of contact person in research-centre	
Email address of contact person in research-centre	
Company information	
Name of the company included in survey.	
Factory (in company) where measurements were done	*
Factory identification number	*
Address of the factory	
Area-code of the factory	
City where factory is located	
Industrial sector (BRMA* coding)	
Contact person at factory	
Total number of workers working in the factory	
Survey information	
Survey identification number	*
Purpose of survey	*
Start of survey (month/year)	*
End of survey (month/year)	*
Organization that did the actual measurements	*
Literature reference	
Sample information	
Identification number of sample	*
Date on which sample was taken (month/day/year)	*
Worker identification number	*
Identification number of stationary sample	*
Part of a repeated measurements series	
Personal, stationary or source-oriented sampling type	*
Process code (BRMA* coding)	*
Department code (BRMA* coding)	*
Batch, continuous or occasional process	*
Temperature of process (in °C)	
Unit of pressure (of process)	
Pressure of process	
Main process done by employee during measurement	*
Machine operated during main process	*
Additional process done during measurements	
Machine operated during additional process	
Second additional process	

Continued

# Core information Machine operated during second additional process Type of rubber used in process (or unknown) In case of mixture: second type of rubber used In case of mixture: third type of rubber used Control measures Measurements taken indoors or outdoors General (room) ventilation/dilution working Open doors or windows Protective equipment used on source (lev. etc.) Type of respirator worn by employee (if any) Type of additional dermal protection worn by employee Rubber chemicals used in powder form Ear protection worn by employee Sampling and analytical methods Name of chemical agent being monitored Additional strategy information for representative sampling Representative or worst-case sampling Sampling device used to measure agent Medium used to collect chemical agent (filter, dermal pad...) Method used to analyse medium Extraction method used Limit of detection for these measurements Unit of measurements Specify standardized method (OSHA/NIOSH...) if used Flow rate (1 min<sup>-1</sup>) Measurement information Measured concentration Exposure pattern (continuous, intermittent, occasionally, unknown) Sampling time (minutes) Measurement concentration is lower than the limit of detection Specific chemical name of solvent that has been measured Specific chemical name of other agent that has been measured Specific nitrosamine that has been measured Standardized 8 h time-weighted average Standardized 8 h twa based upon a 4 h measurement Any additional information about measurement not covered before Part of body where dermal pads were placed Side of the body where dermal pads were placed Name of specific dermal agent that has been measured

### REFERENCES

- Brederode D, Linker F, Marquart H *et al.* (2001) Recording of data of individual measurements of occupational exposure: guideline of the Dutch Society of Occupational Hygiene (October 1999). Appl Occup Environ Hyg; 16: 122–7.
- Burns DK, Beaumont PL. (1989) The HSE National Exposure Database—(NEDB). Ann Occup Hyg; 33: 1–14.
- Burstyn I, Kromhout H, Cruise PJ *et al.* (2000) Designing an international industrial hygiene database of exposures among workers in the asphalt industry. Ann Occup Hyg; 44: 57–66.
- Caldwell DJ, Armstrong TW, Barone NJ *et al.* (2001) Lessons learned while compiling a quantitative exposure database from the published literature. Appl Occup Environ Hyg; 16: 174–7.
- Carlo GL, Jablinske MR, Lee NL et al. (1993) Reduced mortality among workers at a rubber plant. J Occup Med; 35: 611–15.
- Cherrie JW, Sewell C, Ritchie P *et al.* (2001) Retrospective collection of exposure data from industry: results from a feasibility study in the United Kingdom. Appl Occup Environ Hyg; 16: 144–8.
- Dost AA, Redman D, Cox G. (2000) Exposure to rubber fume and rubber process dust in the general rubber goods, tyre manufacturing and retread industries. Ann Occup Hyg; 44: 329–42.
- Fleiss JL. (1981) The measurement of Interrater Agreement. In Fleiss JL, editor. Statistical methods for rates and proportions. (New York, USA: John Wiley and Sons Inc.) ISBN 0-4710-6428-9
- IARC. (1982) IARC Monographs on the evaluation of the carcinogenic risk of chemicals to humans. Volume 28; The Rubber Industry. Lyon, France: International Agency for Research on Cancer.
- IARC. (1987) IARC Monographs on the evaluation of carcinogenic risks to humans: supplement 7. Lyon, France: International Agency for Research on Cancer.
- Kenny L, Aitken R, Chalmers C et al. (1997) Collaborative European study of personal inhalable aerosol sampler performance. Ann Occup Hyg; 41: 135–53.
- Kogevinas M, Sala M, Boffetta P, Kazerouni N, Kromhout H, Hoar-Zahm S. (1998) Cancer risk in the rubber industry: a review of the recent epidemiological evidence. Occup Environ Med; 55: 1–12.
- Kromhout H, Symanski E, Rappaport SM. (1993) A comprehensive evaluation of within- and between-worker components of occupational exposure to chemical agents. Ann Occup Hyg; 37: 253–70.
- Kromhout H, Swuste P, Boleij JS. (1994) Empirical modeling of chemical exposure in the rubber-manufacturing industry. Ann Occup Hyg; 38: 3–22.
- Rajan B, Alesbury R, Carton B *et al.* (1997) European proposal for core information for the storage and exchange of workplace exposure measurements on chemical agents. Appl Occup Environ Hyg; 12: 31–9.
- Rogaczewska T, Ligocka D. (1994) Occupational exposure to coal tar pitch volatiles, benzo/a/pyrene and dust in tyre production. Int J Occup Med Environ Health; 7: 379–86.
- Stamm R. (2000) MEGA-database: one million data since 1972. Appl Occup Environ Hyg; 16: 159–63.
- Stewart PA, Stewart WF. (1994) Occupational case-control studies: II. Recommendations for exposure assessment. Am J Ind Med; 26: 313–26.
- Straif K, Keil D, Taeger D *et al.* (2000a) Exposure to nitrosamines, carbon black, asbestos, and talc and mortality from stomach, lung, and laryngeal cancer in a cohort of rubber workers. Am J Epidemiol; 152: 297–306.
- Straif K, Weiland SK, Bungers M et al. (2000b) Exposure to high concentrations of nitrosamines and cancer mortality

<sup>\*</sup>British Rubber Manufacturers' Association.

- among a cohort of rubber workers. Occup Environ Med; 57: 180-7.
- Straughan JK. (1998) Cancer risk in the rubber industry: a review of recent epidemiological evidence. Occup Environ Med; 55: 1–2.
- Straughan JK, Sorahan T. (2000) Cohort mortality and cancer incidence survey of recent entrants (1982-91) to the United Kingdom rubber industry: preliminary findings. Occup Environ Med; 57: 574–76.
- Szadkowska-Stanczyk I, Wilczynska U, Sobala W et al. (2001) Occupational exposure to chemicals in the manufacture of rubber tires. Med Pr; 52: 401–8.
- Veys CA. (2004) Bladder tumours in rubber workers: a factory study 1946–1995. Occup Med; 54: 322–9.

- Vermeulen R, Bos RP, Kromhout H. (2001) Mutagenic exposure in the rubber manufacturing industry: an industry-wide survey. Mutat Res; 490: 27–34.
- Vermeulen R, de Hartog J, Swuste P *et al.* (2000a) Trends in exposure to inhalable particulate and dermal contamination in the rubber manufacturing industry: effectiveness of control measures implemented over a nine-year period. Ann Occup Hyg; 44: 343–54.
- Vermeulen R, Heideman J, Bos RP *et al.* (2000b) Identification of dermal pathways in the rubber manufacturing industry. Ann Occup Hyg; 44: 533–41.
- Wacker CD, Spiegelhalder B, Borzsonyi M et al. (1987) Prevention of exposure to N-nitrosamines in the rubber industry: new vulcanisation accelerators based on 'safe' amines. IARC Sci Publ; 1987: 370–4.